OVERVIEW OF THE INTEGRATED RISK INFORMATION SYSTEM (IRIS)

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Briefing for ORD Deputy Assistant Administrator (DAA)
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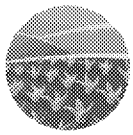
EPA IRIS

- **Created in 1985 to foster consistency in the evaluation of chemical toxicity across the Agency.**
- **IRIS assessment contribute to decisions across EPA and other health agencies.**
- **Toxicity value**
  - Non-cancer: Reference Doses (RfDs) and Reference Concentrations (RfCs).
  - Cancer: Oral Slope Factors (OSFs) and Inhalation Unit Risks (IURs).
- **IRIS assessments have no regulatory impact until they are combined with**
  - Extent of exposure to people, cost of clean-up, available technology, etc.
  - Regulatory options
  - Both of these are the purview of EPA's program offices

IRIS Provides Scientific Foundation for Agency Decision Making

IRIS

- Clean Air Act (CAA)
- Safe Drinking Water Act (SDWA)
- Clean Water Act (CWA)
- Food Quality Protection Act (FQPA)
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Resource Conservation and Recovery Act (RCRA)
- Toxic Substances Control Act (TSCA)



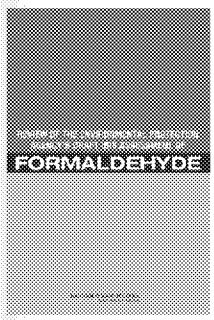
Broad Input to Support

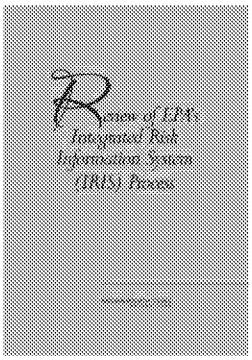
- Agency Strategic Goals
- Children's Health
- Environmental Justice

How Has IRIS Evolved?

- **Full implementation of systematic review to increase transparency**
  - Operationalized approaches that foster consistency across the IRIS Program; many active and all new assessments address systematic review-related recommendations of 2014 NAS report.
- **Modernized the Program**
  - Through applications of specialized software tools, assessments are being conducted faster with significant cost reductions.
  - Major focus on project management software, training, and administration
- **Modularize product lines**
  - Move away from one-size-fits all. Create a portfolio of chemical evaluation products that will allow IRIS to remain flexible and responsive to clients within the EPA as well the diverse collection of stakeholders beyond EPA, including states, tribal nations, and other federal agencies
- **Enhanced accessibility**
  - Provide outreach and training to make systematic review practices ubiquitous and more accessible; enhance data sharing through publicly available software platforms for assessments developed by EPA, other federal and state agencies, industry, academia and other third-parties.

Reports on IRIS





Systematic Review Related

- Method of conducting an assessment that for increases transparency and rigor

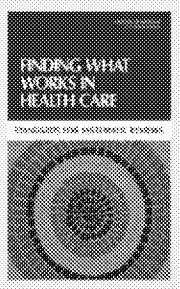
GAO

Accountability * Integrity * Reliability

Focuses on Production Capacity of IRIS to Meet Agency Chemical Assessment Needs

- How do we manage our resources?
- GAO auditors ask about public communication of IRIS priorities
- GAO auditors look for documentation of leadership commitment (at ORD and Agency) levels
- Both IRIS and TSCA on GAO High Risk List

Systematic Review



A structured and documented process for transparent literature review[1,2]

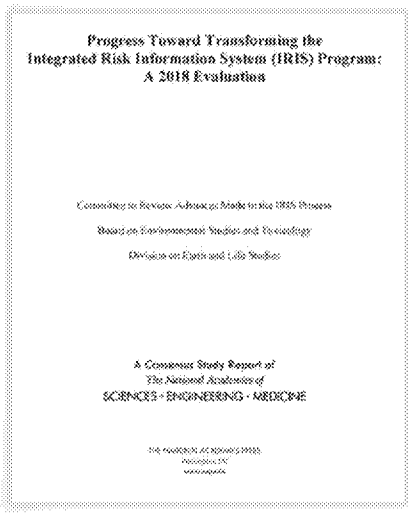
"… systematic review is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent"

[1] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. EPA-HQ-OPPT-2016-0654. https://www.epa.gov/sites/production/files/2017-06/documents/prepubcopy_tsca_riskeval_final_rule_2017-06-22.pdf

[2] Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p.13-34. The National Academies Press. Washington, D.C. 2011

Systematic Review Progress

- **NAS IRIS Workshop February 1-2, 2018 - A consensus report is now available**


Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation

A Consensus Study Report of The National Academies of SCIENCES • ENGINEERING • MEDICINE

- "Overall, the committee was impressed with the changes being instituted in the IRIS program since the 2014 report.
- The change in NCEA and IRIS leadership has led to substantive reforms, and there is strong evidence that systematic review methods are being developed and implemented and that there is a commitment to use systematic-review methods to conduct IRIS assessments.
- Its overall conclusion is that EPA has been responsive and has made substantial progress in implementing National Academies recommendations."

Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation

Systematic Review: IRIS Handbook

- Describes the systematic review and dose-response methods IRIS uses to conduct assessments
  - 200+ pages aimed at staff level SOPs
- High visibility (Congressional budget language, NAS reports, OMB, GAO, external stakeholders)
- Peer-review for the IRIS Handbook is similar to that used for a chemical assessment (2 rounds Agency review, interagency review, public comment, external peer-review)

Deliberative Process / Ex. 5

Prior GAO Engagements

- **EPA's IRIS Program was added to the "High Risk" list in 2009, along with TSCA under the broader topic *Transforming EPA's Processes for Assessing and Controlling Toxic Chemicals*:**
  - Because EPA had not developed sufficient chemical assessment information under these programs to limit exposure to many chemicals that may pose substantial health risks.
- **GAO 2017 Report acknowledged the actions ORD has taken to enable the IRIS Program to produce timely, transparent, and credible assessments in support of EPA's mission.**

Summary of 2015 and 2017 GAO High Risk Criteria Ratings of the IRIS Program		
GAO High Risk Criteria	2015 Rating	2017 Rating
Leadership Commitment	Met	Met
Monitoring	Partially Met	Met
Action Plan	Partially Met	Partially Met
Demonstrated Progress	Not Met	Partially Met
Capacity	Not Met	Partially Met

Current GAO Engagement

- **Subject: "EPA's Chemical Management Strategies" (code 102673)**
- **GAO began this work on its own initiative pursuant to its authority under 31 U.S.C. 717**
- **GAO objectives:**
  - To what extent has EPA demonstrated progress assessing chemicals through the Integrated Risk Information System (IRIS) program and how have recent changes to the program addressed underlying challenges?
  - To what extent has EPA demonstrated progress implementing the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act, and ensured that EPA has the resources necessary
- **Engagement initiated March 2018, report expected early 2019**

Understanding Agency Needs

- **Now evaluating Program and Regional offices continued need for and interest in existing assessment products in the IRIS pipeline (aka "IRIS memo" survey process),**
  - Survey responses include outlining the regulatory decision-making context, priority and timeline, and additional information to support assessment development.
- **New priority areas of interest are also being identified.**
- **Project/program management to calibrate resource commitments.**
- **Monthly EPA-wide calls for routine bi-directional updates.**
- **Frequent chemical-specific micro-updates to the offices/regions around critical milestones in assessment development.**

IRIS Program Staffing

- **IRIS Division**
- **IRIS Program**
  - Implemented as a team matrix across NCEA (IRIS Division, Washington Division, RTP Division, and Cincinnati Division)
  - Efficient managing of staff resources of the IRIS program relies on project management software and staff oversight
- **Assessment Teams**
  - ~4-6 staff with a range of expertise tailored to meet the needs of specific chemical (e.g., epidemiologists, animal toxicologists, pharmacokinetic modelers, cancer, etc.)
  - Staff work on multiple assessments and there is currently minimal use of contractors
- **Staffing matrix has implications for considering the Improving Science in Chemical Assessments Act (H.R. 6468)**

IRIS Project Management

Deliberative Process / Ex. 5

MS Project Online allows

- Tracking resource assignments and project milestones across assessments
- Individual project schedule management
- Development of schedules from an enterprise template
- Connection to desktop software
- Staff can easily update their assignment status

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

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